

21635  
LMP

UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: Box ISSUE FEE  
COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

RECEIVED

JUL-0-2 1990

BANNER, BIRCH

BANNER, BIRCH, MCKIE & BECKETT  
ONE THOMAS CIRCLE NW  
WASHINGTON, DC 20005

**NOTICE OF ALLOWANCE  
AND ISSUE FEE DUE**

- Note altered communication from the Examiner  
 This notice is issued in view of applicant's communication filed \_\_\_\_\_

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
07/055,942	06/01/87	006	CUNNINGHAM, T	136 06/29/90

First Name(s)  
Applicant

CIVIN,

CURT I.

TITLE OF  
INVENTION

HUMAN STEM CELLS AND MONOCLONAL ANTIBODIES

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
21635	435-240,270	G68	UTILITY	NO	\$620.00	10/01/90

*Issue Fee Due 6/29/90*  
**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.  
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS  
APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY Status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the Status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by a charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

**IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees.**

(REV 12-88)(OMB Clearance is pending)

YOUR COPY



UNITED STATES PATENT AND TRADEMARK OFFICE  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

#15

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
18/	

DATE MAILED:

## NOTICE OF ALLOWABILITY

## PART I.

1.  This communication is responsive to the amendment filed 6/27/90  
2.  All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.  
3.  The allowed claims are Claims 2, 4, 5, 7, 9, and 10  
4.  The drawings filed on \_\_\_\_\_ are acceptable.  
5.  Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [...] been received. [...] not been received. [...] been filed in parent application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_  
6.  Note the attached Examiner's Amendment.  
7.  Note the attached Examiner Interview Summary Record, PTOL-413.  
8.  Note the attached Examiner's Statement of Reasons for Allowance.  
9.  Note the attached NOTICE OF REFERENCES CITED, PTO-892.  
10.  Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

## PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1.  Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2.  APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
  - a.  Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. \_\_\_\_\_. CORRECTION IS REQUIRED.
  - b.  The proposed drawing correction filed on \_\_\_\_\_ has been approved by the examiner. CORRECTION IS REQUIRED.
  - c.  Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
  - d.  Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

## Attachments:

- Examiner's Amendment
- Examiner Interview Summary Record, PTOL- 413
- Reasons for Allowance
- Notice of References Cited, PTO-892
- Information Disclosure Citation, PTO-1449
- Notice of Informal Application, PTO-152
- Notice re Patent Drawings, PTO-948
- Listing of Bonded Draftsmen
- Other

TMC

MARGARET MOSKOWITZ  
SUPERVISORY  
PATENT EXAMINER  
ART UNIT 196

REASONS FOR ALLOWANCE

i. The Section 112, first paragraph ('scope of enablement') rejection has been obviated by the amended claim language which limits the claimed monoclonal antibodies to species that react with a particular antigen (now identified as CD-34). In view of the deposit of the hybridoma (HB-8483) producing a monoclonal antibody reactive with this antigen, the unpredictability argument regarding production of other such antibodies is mooted.

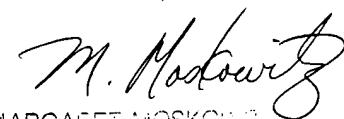
2. The §102(b) rejection is withdrawn. While the references relied upon AS (Civin, 1982) and AT (Civin, 1982) teach monoclonal antibodies to the KG-1A cell line which recognize the determinant identified by MY-10 they do not provide an enabling disclosure. The MY-10 determinant is inadequately characterized as to its inherent molecular mass. The MY-10 determinant is identified to be of a mass of 95 kDa. In fact, the determinant recognized by the MY-10 antibody is much closer to 115 kDa. One with skill in the art would not be able to isolate or identify monoclonal antibodies to this determinant based on the disclosure of AS or AT. Additionally, neither of these references teach the particular specificity of monoclonal antibodies to this determinant.

3. The §103 rejection over Nadler is withdrawn in view of the evidence filed in Paper No. 14. This papers filed with Paper No. 14 further evidence that the particular antigen identified by the claimed monoclonal antibodies was unknown to the prior art. While the KG-1A cell line (which bears determinants recognized by the claimed monoclonal antibodies) was known and methods of producing monoclonal antibodies were known, the identity of the particular antigen and antigenic determinant identified by the claimed monoclonal antibodies was not disclosed by the Nadler reference. One with ordinary skill in the art would not have a reasonable expectation of being able to identify and produce a monoclonal antibody to a previously

unknown antigen. Therefore, the claimed monoclonal antibodies and hybridomas are not obvious over the prior art of record (which does not teach the particular antigen identified).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Thomas Cunningham, Ph.D whose telephone number is (703) 557-5264. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-0664.

TMC  
Cunningham  
6/26/90



MARGARET MOSKOWITZ  
GROUP SUPERVISOR  
PATENT EXAMINER

Application Serial No.  
Art Unit 186

**Examiner's Amendment**

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

- A. Cancel claims 1, 3, 6, 8, and nonelected claims 11-22 and 27-30.
- B. In claim 2 (Paper No. 16), line 4 change "recognized" to  
--specifically bound--.
- C. In claim 4 (Paper No.16), line 2 change "recognizes" to  
--specifically binds--.
- D. In claim 4 (Paper No.16), line 3, change "recognized" to  
--specifically bound--.

2. Authorization for this Examiner's Amendment was given in a telephone interview with Dale Hoscheit on June 28, 1990.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Thomas Cunningham whose telephone number is (703) 557-5264. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-0664.

*M. Moskowitz*  
MARGARET MOSKOWITZ  
SUPERVISORY EXAMINER  
RECEIPTED 6/28/90

*TMC*  
Cunningham  
6/28/90